ATTACHMENT 4

GUIDELINES FOR PREPARING THE ABSRACT SUMMARY

An abstract summarizing each of the following items must be included with each application before it will be processed for Board review. The Abstract Summary must be single spaced and limited to no more than three pages. If an item is not applicable, please note accordingly.

AN ABSTRACT SUMMARY MUST ALSO BE PREPARED FOR RESEARCH SUBMITTED AS EXEMPT

1. Briefly summarize the purpose of this study including the methods and procedures to be used.

2. Describe the source for the study population and what is required of the subjects. (when the population consists of special groups such as prisoners, children and the mentally disabled or other groups whose ability to give voluntary informed consent may be in question, it is necessary to provide the rationale for using this particular population.)

3. State if the activity requires the use of records (hospital, medical, birth, death or other), organs, tissues, body fluids, a fetus or an abortus.

   If identifying information is to be collected from records, indicate the type of data to be retained, the purpose for which the data will be used, how long it will be retained in identifiable form, and how the disposition of the data will be handled.

4. Describe and assess any potential risks - physical, psychological, social, legal or other and assess the likelihood and seriousness of such risks.

   a. Describe procedures for protecting against or minimizing potential risks and assess their likely effectiveness.

   b. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.

5. Assess the potential benefits to be gained by the individual subjects as well as the benefits which may accrue to society in general as a result of the planned work. Indicate how the benefits outweigh the risks.

6. Describe consent procedures to be followed, including how and where informed consent will be obtained. When there are potential risks to the subject, or the privacy of the individual is involved, the investigator is required to obtain a signed informed consent statement from the subject. For subjects who are not able to give informed consent, signed informed consent must be obtained from the parent or authorized legal guardian of the subject. These subjects should be provided with information clearly stating what is to be expected in order that they may assent to participation. <u>Furnish an actual copy of the disclosure statement and/or the informed consent statement.</u>

   a. If signed informed consent will not be obtained, explain why this requirement should be waived and provide an alternative procedure.

   b. If information is to be withheld from a subject, justify this course of action.

7. Describe the method for safeguarding confidentiality and/or measures for protecting anonymity. (Inform the Board where the data will be kept and plans for disposition at the completion of the study.)

8. If the study will involve an interview, describe where and in what context the interview will take place. (The approximate length of time required for the interview should be stated in the consent form.)

9. If the final survey instrument is not submitted with the IRB Form I (Attachment 3), the following information should be included in the abstract summary:

   a. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy;

   b. Examples of the type of specific questions to be asked in the sensitive areas; and

   c. Indicate when the questionnaire will be presented to the Board for review.